IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Clark R. Baker, Jr.	§	Confirmation No.:	1106
Serial No.: 10/796,584	§	Group Art Unit:	3777
Filed: March 8, 2004	§	Examiner:	Ramirez, John Fernando
For: Method and Apparatus for Optical Detection of Mixed Venous and Arterial Blood Pulsation in Tissue	§	Atty. Docket:	TYHC:0149/FLE/POW P0409R

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February 11, 2011	/W. Allen Powell/
Date	W. Allen Powell

Sir:

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

The Appellant submits this Reply Brief in response to the Examiner's Answer mailed on December 14, 2010, pursuant to 37 C.F.R. § 41.41. The Examiner's position, as set forth in the Grounds of Rejection section of the Reply Brief, appears to be substantially unchanged relative to the last Office Action, which was issued on July 9, 2010. In this brief, the Appellant specifically addresses the arguments raised in the Examiner's Answer.

The Examiner's Answer maintains the rejection of claims 1–4, 6–16, and 18–22 under 35 U.S.C. § 103(a) as being obvious over Diab et al. (U.S. Publication No. 2003/0036689; "Diab") in view of Swedlow et al. (U.S. Patent No. 5,662,106; "Swedlow") and further in view of non-patent literature "*Masimo Signal Extraction Pulse Oximetry*" ("Masimo"). However, none of these references, whether taken alone or in combination, disclose detecting the specific phenomenon of venous pulsation. As discussed in the Application, detecting venous pulsation is important because it is a problem a clinician can address by, for example, tightening a sensor on the patient. Moreover, merely detecting the presence of general noise is not the same as specifically detecting venous pulsation.

As set forth throughout the prosecution history and in the Application, embodiments of the above-referenced application are directed to the field of pulse oximetry, and in particular, to processing pulse oximetry signals to detect the presence of a phenomenon known as "*venous pulsation*." Application, ¶¶ 1 and 4. Venous pulsation is an undesirable artifact in pulse oximetry. *Id.* ¶ 38. The Application explains that "[u]nlike motion artifacts that may not be present at all times (*e.g.*, they come and go), venous pulsation can continue uninterrupted for hours." *Id.* ¶ 39. Moreover, unlike general noise, venous pulsation has particular characteristics: "Other artifacts, such as motion and noise may add out-of-phase components whose phase relationship and frequency content is unstable, and not as persistent as the venous pulsation induced phase difference." *Id.* ¶ 42. Finally, the application explains that it is valuable to distinguish venous pulsation from other types of noise because "[v]enous pulsation at the site of the oximetry sensor may be mitigated by applying pressure to the site, such as with a headband." *Id.* ¶ 39. "The detection of the presence of venous pulsation enables an oximeter to display a troubleshooting message to a clinician, who could then address and/or correct the problem." *Id.* ¶ 40. "It is therefore desirable that a pulse oximetry system be designed which effectively and accurately detects and/or notifies a clinician of the presence of venous pulsation." *Id.* ¶ 4.

Accordingly, present embodiments are directed to detecting the presence of venous pulsation so that a caregiver may be notified and take measures to prevent further venous pulsations (*e.g.*, via tightening of the sensor on the patient). For example, independent claims 1 and 13 each recite "detecting the presence or absence of *venous pulsation*" and "indicating the presence of *venous pulsation*." (Emphasis added).

As the Appellant has noted throughout prosecution, the noise detection methods in Diab are directed towards general purpose noise, not venous pulsation. For example, paragraph 19 of Diab explains that "the secondary portion [of the pulse oximetry signal] also includes artifacts due to patient movement which causes the venous blood to flow in an unpredictable manner, causing unpredictable attenuation and corrupting the otherwise periodic plethysmographic waveform." Diab ¶ 19.

The Examiner cites paragraphs 389–396, 387, and 368 and Figure 25B from Diab to show the detection of venous pulsation. As a preliminary matter, none of the cited paragraphs even mention the concept of venous pulsation. Nor do they disclose the limitations in independent claims 1 and 13 for detecting it.

Paragraphs 389–396 of Diab do not disclose calculating "the phase difference between the red and infrared *signals*" as the Examiner asserts. Instead, they disclose calculating the "difference in phase *between the corresponding data points* from the phase modules **690**, **692**" and comparing that difference to a threshold. Diab ¶ 389. This calculation is done only for the purpose of qualifying or disqualifying *individual data points* for use in a subsequent saturation calculation. *Id.* ¶ 388–93 ("For *those sample points* which qualify, a ratio is taken in the ratio module **670**. For those *points* which do not qualify, the saturation is set to zero at the output of the saturation equation **672**."). Indeed, Diab indicates that "[i]f the phase of two corresponding sample points is too far apart, then the sample points are not used." *Id.* ¶ 389. Thus, Diab expressly contemplates that phase differences in sample points may vary substantially from point-to-point such that some points may qualify while others will not. Further, when there is a substantial phase difference, the sample points are disregarded.

Diab does not explain how this multitude of point-by-point operations can "obtain a measure of a phase difference between the first and second electromagnetic radiation *signals*" as required by claims 1 and 13. Nor does Diab explain how to use such measurements to detect the specific phenomenon of venous pulsation. As discussed above, venous pulsation is characterized by persistent phase differences. Application ¶ 42. At best, the disclosure of Diab is directed to dealing with the "unstable" out of phase components that the Application associates with general purpose noise and motion artifacts, not venous pulsation. *See id.* And this process is only used to decide which signal points to use in calculating arterial

saturation. The remainder of the disclosure in paragraphs 389–396 of Diab explains how to find the arterial saturation and the pulse rate (which is the rate of pulsation of the arterial blood), not venous pulsation.

Figure 25B of Diab illustrates the point-by-point calculations discussed in paragraphs 389–396—as well as the magnitude threshold discussed below—but does not disclose detecting venous pulsation. The drawings of the cited reference must be evaluated for what they *reasonably* disclose and suggest to *one of ordinary skill in the art. See In re Aslanian*, 590 F.2d 911, 200 U.S.P.Q. 500 (C.C.P.A. 1979). Appellant asserts that one of ordinary skill in the art would not interpret Fig. 25B of Diab as disclosing the detection or indication of the presence of *venous pulsation*. Rather, as would be expected based on other portions of Diab, Fig. 25B is directed to "yet another alternative embodiment in order to obtain *saturation*." Diab, ¶ 74, (emphasis added). Indeed, there is nothing in Fig. 25B of Diab that suggests any relation to *venous pulsation*. While the text "pulse calculation" is present in Fig. 25B, it is clear that the "pulse calculation" refers to obtaining a "pulse rate" (not detecting or indicating venous pulsation). *See* Diab, ¶¶ 397 and 399-400. For example, paragraph 97 of Diab states that "the input to the window function module **700** is obtained from the output of the complex FFT modules **652** or **654**," and paragraph 400 states that, "[i]n order to obtain *pulse rate*, the output points from the window function module **700** are provided to a spectrum analysis module **702**." (Emphasis added). Thus, one of ordinary skill in the art clearly would *not* find that Fig. 25B of Diab *reasonably* discloses or suggests anything related to venous pulsation.

Paragraph 387 of Diab discusses setting a threshold for the *magnitude* of red and infrared data points, not the phase, as required by claims 1 and 13. Diab ¶ 387 ("The threshold modules **660**, **662** examine the sample points, on a point-by-point basis, to select those points where the magnitude of an individual point is above a particular threshold . . ."). And finally, paragraph 368 of Diab simply makes reference to a general noise signal "n" that contains "information on the venous blood, as well as motion artifacts and other noise." Paragraph 368 does not explain how, if it is possible at all, to detect venous pulsation based on the noise signal.

In view of the remarks set forth above, Appellant again stresses that the cited references simply do not disclose detecting or indicating the presence of *venous pulsation*. Indeed, there is a complete lack of any discussion whatsoever regarding detecting the

presence or absence of venous pulsation in the cited references. Thus, Appellant asserts that the Examiner's rejection of claim 1 and 13, and the claims respectively depending therefrom, should be overturned.

Further, in the Examiner's Answer, the Examiner reiterated previous arguments with regard to dependent clams 2 and 14. In this regard, Appellant stresses that dependent claim 2 recites, *inter alia*, "filtering the first and second electromagnetic radiation signals before the obtaining the measure, to pass portions of the first and second electromagnetic radiation signals *having frequencies at or near the pulse rate or harmonics of the pulse rate* of the blood perfused tissue," and dependent claim 14 includes similar language. (Emphasis added). The Examiner has maintained that paragraphs 329 and 385 of Diab disclose these features. Examiner's Answer, p. 6. However, the cited paragraphs merely appear to include a general discussion of a spectrum analysis module 590 and utilization of a complex FFT, which includes utilization of high-pass filter modules 645, 647. Further, these filter modules 645, 647 do *not* appear to pass portions of the radiation signals with specific frequencies related to the patient's pulse rate, as recited in claims 2 and 14.

On page 6 of the Examiner's Answer, the Examiner asserted, "With respect to claims 3-4 and 15-16, Diab et al. illustrates in figures 26-30 the measurement of both signals red and infrared, in which each of the signals is relatively undisturbed by motion artifact over a time period (pars. 0411-0414)." Appellant reiterates that the drawings of the cited reference must be evaluated for what they *reasonably* disclose and suggest to *one of ordinary skill in the art*. *See In re Aslanian*, 590 F.2d 911, 200 U.S.P.Q. 500 (C.C.P.A. 1979). Further, Appellant asserts that it is not clear to Appellant that the cited portion of Diab discloses what the Examiner alleges. However, even if Diab discloses that both red and infrared signals are measured while relatively undisturbed by motion artifact over a time period, this does not address the recitations of claims 3, 4, 15, and 16. Dependent claims 3 and 15 each recite, *inter* alia, "obtaining a measure of a persistent phase difference between the first and second electromagnetic signals." Dependent claims 4 and 16 each recite, *inter alia*, "integrating the measure of a phase difference over a time period." It is unclear to Appellant why the Examiner has asserted that Diab addresses these claim features by allegedly disclosing that both red and infrared signals are measured over a time period while relatively undisturbed by

motion artifact. Accordingly, Appellant asserts that Diab fails to disclose the recited features of claims 3, 4, 15, and 16.

With regard to claims 6 and 18, the Examiner asserted that paragraph 14 of Diab discloses "a method for analyzing and correlating the measured signals." Examiner's Answer, p. 7. Paragraph 14 of Diab states that "a signal processor acquires a first measured signal and a second measured signal that is correlated to the first measured signal." Diab, ¶ 14. However, claim 6 recites, *inter alia*, "analyzing a cross-correlation function of the first and second electromagnetic radiation signals, *as a function of a delay interval between them*," and claim 18 recites similar language. (Emphasis added). Appellant maintains that there is no indication in Diab that a correlation function is analyzed as a function of a delay interval between the radiation signals, as required by claims 6 and 18.

With regard to claims 8 and 20, the Examiner merely asserted that "the subtracting step by taking the complex conjugate of the signals and dividing by the product of the magnitudes of the signals, it would have been an obvious design choice for one of ordinary skill in the art." Examiner's Answer, p. 7. This is merely an unsupported assertion by the Examiner. Nothing in the cited references discloses the features recited by claims 8 and 20. Indeed, nothing in the cited references appears to suggest or relate to taking the complex conjugate and dividing the complex conjugate by the product of the magnitudes of the radiation signals. In view of this, Appellant reiterates that the Examiner has improperly taken Official Notice. Accordingly, Appellant believes claims 8 and 20 are clearly allowable over the cited references.

Appellant asserts that all pending claims are in condition for allowance. None of the art cited by the Examiner discloses either detecting or reporting venous pulsation, as required by independent claims 1 and 13. For this reason, and the others set forth above and in the previously submitted Appeal Brief, Appellant respectfully requests that the Board overturn the Examiner's rejection.

Respectfully submitted,

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